REMARKS:

Applicant has carefully studied the nonfinal Examiner's Action and all references cited therein. The amendment appearing above and these explanatory remarks are believed to be fully responsive to the Action. Accordingly, this important patent application is now believed to be in condition for allowance.

Applicant responds to the outstanding Action by centered headings that correspond to the centered headings employed by the Office, to ensure full response on the merits to each finding of the Office.

Objection to Information Disclosure Statement

The Office has indicated that the information disclosure statement filed on 12/23/02 has been considered, but that the articles were not initialed on the PTO-1449 form because the articles are missing the name of the journal, the date and pages. A supplementary IDS has been submitted along with this amendment, providing the missing information as requested.

Objection to Specification

The Office has objected to the arrangement of the specification. Accordingly, this amendment includes a request to relocate the cross-reference section as required.

Claim Rejections – 35 U.S.C. § 112

Applicant acknowledges the quotation of 35 U.S.C § 112, first paragraph.

Claims 1, 2 and 9-11 stand rejected under 35 U.S.C § 112, first paragraph. The Office states that the claims as presented do not reasonably provide enablement for a method of treating a tumor in vivo comprising introducing at least one exogenous nucleic acid to at least one tumor using a genus of administration routes and applying an energy source to the at least one exogenous nucleic acid. The Office concludes that the specification does not enable any person

skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The Office has concluded that the claimed invention lies in the field of cancer gene therapy. The Office provides a discussion of the state of the art of cancer gene therapy, citing several references. The Office has determined that at the time the application was filed, the state of the art for gene therapy was considered highly unpredictable. As such, the Office concludes that given the lack of sufficient guidance as to a gene therapy effect produced by any nucleic acid cited in the claims, one skilled in the art would have to engage in a large quantity of experimentation in order to practice the claimed invention based on the applicants' disclosure and the unpredictability of gene therapy.

Applicant respectfully traverses the finding of the Office regarding the rejection of claims 1, 2 and 9-11 under U.S.C. 112, first paragraph.

The present invention does not lie in the field of cancer gene therapy. In general, gene therapy is the transfer of genetic information into cells and tissues to achieve some desired effect. In humans, gene therapy is typically used to treat or compensate for a genetic mutation in the cellular genetic machinery or to enhance the production of a certain protein. The steps in gene therapy include, isolating the gene coding for the desired protein, delivering the gene to a target cell by means of a vector, integrating the gene into the cell such that the cell begin to produce DNA and RNA coding for the protein, the protein produced by the cell then acts inside the cell or is released into the environment and then stimulates the desired action.

The present invention does not describe a method of treating cancer through gene therapy. As previously described, gene therapy requires that the gene that is introduced to a target cell be a gene that codes for a desired protein, such that the protein is produced by the cell upon an effective treatment procedure. By contrast, the gene that is delivered to a tumor cell in accordance with the present invention is a non-native gene. As described at paragraph [0030] of the specification, a non-native gene is a gene that does not code for a known transcription or translation product for the particular species receiving treatment. As such, a non-native gene in accordance with the present invention may be defined as a non-coding nucleic acid sequence that does not code for a therapeutic protein of the species.

Claim 1 has been amended to more clearly describe that which the applicant regards as the invention. Amended claim 1 describes a method of eliciting an antitumor effect in vivo comprising the steps of, identifying a species representative of a treatment subject, identifying at least one non-coding nucleic acid sequence of the species, wherein the non-coding nucleic acid sequence does not code for a therapeutic protein of the species, introducing the at least one non-coding nucleic acid to at least one tumor cell in the treatment subject, applying energy from an energy source to the at least one tumor cell, the application of the energy effective in eliciting an antitumor effect.

Applicant believes that the specification does enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with the claims, and as such, the specification is enabling for claims 1, 2, and 9-11 as presented.

Claim Rejections – 35 U.S.C. § 112

Applicant acknowledges the quotation of 35 U.S.C § 112, second paragraph.

Claims 6-8 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the Office states that claim 6 does not define the active step for the phrase, "wherein the energy source is adapted to make permeable at least one cell in the at least one tumor", and that there is not nexus between the energy source and the cell in the tumor.

Claims 6-8 have been amended to more clearly describe that which the applicant regards as the invention. Accordingly, the amended claims provide a nexus between the energy source and the cell in the tumor.

Claim Rejections – 35 U.S.C. § 102

Applicant acknowledges the quotation of 35 U.S.C § 102(a), 102(b) and 102(e).

Claims 1and 2 stand rejected under 35 U.S.C § 102(a) as being anticipated by Heller et al. (Melanoma Research 2000, 10, pp. 577-583).

The Office states that claims 1 and 2 read on a method of treating a tumor in a subject comprising administering a heterologous nucleic acid to at least one tumor and applying electroporation to the tumor comprising the nucleic acid.

Applicant respectfully traverses the finding of the Office. Applicant has been unable to determine where in the Heller reference a "heterologous nucleic acid" is described as cited by the Office. However, the Heller is clear on the point that the application of electric pulses to tumors after the injection of a plasmid DNA is for the purpose of enhancing plasmid expression, and are therefore by definition coding nucleic acids.

By contrast, as previously described, the present invention describes and claims the use of non-coding nucleic acids for a species. As such, the present invention is not anticipated by Heller et al. (Melanoma Research 2000, 10, pp. 577-583).

Claims 1 and 2 stand rejected under 35 U.S.C. 102(e) as being anticipated by Monahan et al., (U.S. 6,630,351).

The Office contends that claims 1 and 2 of the present invention read on a method of treating a tumor in a subject comprising administering a heterologous nucleic acid and that Monahan teaches administering a compound comprising a heterologous nucleic acid and a polymer with a labile group to the intracellular and/or extracellular environment of a cell and applying electroporation to the cell, wherein the cell is a tumor in a subject, at column 4, 17 and 24.

Applicant respectfully traverses the finding of the Office. Again, Applicant is unable to identify the use of the term "heterologous" in the reference. However, the term heterologous is commonly used in biology to identify something that is derived from a different species. The term heterologous nucleic acid is not equivalent to a non-coding nucleic acid as described and claimed by the present invention. In view of this description of the prior art by the Office, the Applicant reveals that Monahan describes at column 4, 17 and 24 a gene therapy technique requiring the use of genes expressing for a particular protein, which does not anticipate the use of non-coding nucleic acids to elicit antitumor effects as described by the present invention.

Claims 1 and 2 are rejected under 35 U.S.C. 102(e) as being anticipated by Maclaughlin et al. (U.S. 2002/0102729).

The Office contends that claims 1 and 2 of the present invention read on a method of treating a tumor in a subject comprising administering a heterologous nucleic acid and contends that Mclaughlin teaches delivering a formulation comprising a heterologous nucleic acid to tumor cells in vivo and using electroporation on the cell to enhance delivery of the nucleic acid to the cells at pages 1 and 10-11.

Applicant respectfully traverses the finding of the Office. The Office has incorrectly interpreted the limitation of a "non-native" nucleic acid to be biologically equivalent to a "heterologous" nucleic acid. Mclaughlin clearly describes at paragraph [0120], pg. 10, the use of electroporation for gene therapy, requiring an immune response to the protein encoded by the injected nucleic acid. As such, Mclaughlin does not describe the use of a non-coding nucleic acid for eliciting an antitumor response as described and claimed by the present invention.

Claims 1, 2 and 11 stand rejected under 35 U.S.C. 102(b) as being anticipated by Nicolau et al., (WO 97/07826).

The Office contends that claims 1 and 2 of the present invention read on a method of treating a tumor in a subject comprising administering a heterologous nucleic acid and that Nicolau teaches delivering a foreign nucleic acid to tumors in vivo and using electroporation on the tumors at pages 1 and 6-8.

Applicant respectfully traverses the finding of the Office. Nicolau describes at page 1 a method for treating cells, in vivo, by introducing foreign nucleic acid by electroporation to cause suppression or expression of at least one protein. As described on page 3, the foreign nucleic acids, such as genes, are introduced into the cells for gene therapy to alter a genetic characteristic of the cells. Accordingly, the foreign nucleic acids as described by Nicolau are coding. As such, Nicolau does not describe the use of a non-coding nucleic acid for eliciting an antitumor response as described and claimed by the present invention.

Claims 1, 2, and 11 stand rejected under 35 U.S.C. 102(e) as being anticipated by Heller et al., (U.S. 6,714,816).

The Office contends that claims 1 and 2 of the present invention read on a method of treating a tumor in a subject comprising administering a heterologous nucleic acid and that Heller teaches delivering nucleic acids to tumor cells in vivo and using electroporation on the tumor cells at columns 3 and 8-12.

Applicant respectfully traverses the finding of the Office. Heller describes at col. 3, an improved system and method for delivering molecules to cells in vivo. While Heller describes the method to be effective in the delivery of a variety of types of molecules, Heller does not describe the delivery of a non-coding nucleic acid. As such, Heller does not describe the use of a non-coding nucleic acid for eliciting an antitumor response as described and claimed by the present invention.

Claims 1, 2 and 11 are rejected under 35 U.S.C. 102(e) as being anticipated by Dev et al., (U.S. 6,569,149).

The Office contends that claims 1, 2 and 11 of the present invention read on a method of treating a tumor in a subject comprising administering a heterologous nucleic acid and that Dev teaches delivering nucleic acids to tumor cells and using electroporation on the tumor cell at columns 14-18.

Applicant respectfully traverses the finding of the Office. Dev does not describe the use of a non-coding nucleic acid for eliciting an antitumor response as described and claimed by the present invention. As such, the present invention is not anticipated by Dev et al.

Claims 1 and 2 stand rejected under 35 U.S.C. 102(e) as being anticipated by Heller et al., (U.S. 6,135,990).

The Office contends that claims 1 and 2 of the present invention read on a method of treating a tumor in a subject comprising administering a heterologous nucleic acid and that Heller teaches delivering nucleic acids to tumor cells and using electroporation on the tumor cells at column 3.

Applicant respectfully traverses the finding of the Office. Heller does not describe the use of a non-coding nucleic acid for eliciting an antitumor response as described and claimed by the present invention. As such the present invention is not anticipated by Heller et al.

Claims 1 and 2 stand rejected under 35 U.S.C. 102(e) as being anticipated by Gilbert et al. (U.S. 6,314,316).

The Office contends that claims 1 and 2 of the present invention read on a method of treating a tumor in a subject comprising administering a heterologous nucleic acid and that Gilbert teaches delivering nucleic acids to tumor cells and using electroporation at columns 2 and 3.

Applicant respectfully traverses the finding of the Office. Gilbert does not describe the use of a non-coding nucleic acid for eliciting an antitumor response as described and claimed by the present invention. As such the present invention is not anticipated by Gilbert et al.

Claims 1, 2 and 11 stand rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter. The Office has cited the following references in support of the 35 U.S.C. 102(f) rejection: Heller et al. (U.S.6,714,816), Dev et al. (U.S. 6,569,149), Heller et al. (U.S. 6,135,990), Gilbert et al. (U.S. 6,314,316), Jaroszeski et al. (U.S. Application 09/939,518). In these rejections, the Office concludes that although the cited references do not specifically recite a nucleic acid as the molecule or the cell as the tumor cell, in view of the specifications, the claims read on the claims of the present invention.

Applicant respectfully traverses the finding of the Office. The Office has incorrectly stated in the 102(f) rejections that the claims of the present invention are directed to delivering nucleic acids into a tumor cell in vivo using electroporation. However, the claims of the present invention include the express limitation of delivering a non-coding nucleic acid, which is not believed to be anticipated by the cited references. As such, the present invention is not anticipated by Heller et al. (U.S.6,714,816), Dev et al. (U.S. 6,569,149), Heller et al. (U.S. 6,135,990), Gilbert et al. (U.S. 6,314,316) or Jaroszeski et al. (U.S. Application 09/939,518).

Claim Rejections – Double Patenting

Claims 1, 2 and 11 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-14 of U.S. Patent No. 6,714,816, claims 1, 2 and 3 of U.S. Patent No. 6,569,149, claims 17-28 of U.S. Patent No. 6,135,990, claims 11-15 of U.S. Patent No. 6,314,316 and claims 1, 11, 45 and 51 of copending Application No. 09/939,518. As such, the Office has concluded that claims 1, 2, and 11 of the present invention are not patentably distinct from the conflicting claims cited in the references. In summary of the rejection, the Office contends that while the conflicting claims are not identical, they are not patentably distinct from each other because the claims from the instant application are directed to a method of treating a tumor in a subject comprising administering at least one heterologous nucleic acid to at least one tumor and using electroporation on the tumor. The Office states that the only differences between the claims of the instant application and the conflicting claims is that the conflicting claims do not recite wherein the tissue is a tumor and wherein the molecule is a nucleic acid, but that in light of the teachings of the specification, the specification defines the molecules as a nucleic acid and the tissue as a tumor.

Applicant respectfully traverses the finding of the Office. The Office has incorrectly concluded that claims 1, 2 and 11 are directed to a method of treating a tumor comprising administering at last one heterologous nucleic acid to a tumor. The claims of the present invention are not directed to the delivery of a heterologous nucleic acid, but to the delivery of a non-coding nucleic acid, which are by definition distinct. As such, the claims of the present invention are patentably distinct from the conflicting claims presented by the Office in this double patenting rejection.

For the reasons cited above, Applicant believes that amended independent claim 1 is patentable and is believed to be in condition for allowance.

Claim 2 and claims 6-11 are dependent upon claim 1, and are therefore allowable as a matter of law.

If the Office is not fully persuaded as to the merits of Applicant's position, or if an Examiner's Amendment would place the pending claims in condition for allowance, a telephone call to the undersigned at (727) 507-8558 is requested.

Very respectfully,

SMITH & HOPEN

By: _____

Dated: October 28, 2004

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Attorney for Applicant

CERTIFICATE OF FACSIMILE TRANSMISSION
(37 C.F.R. 1.8(a))

I HEREBY CERTIFY that this Amendment A is being transmitted by facsimile to the United States Patent and Trademark Office, Art Unit 1635, Attn.: Brian A. Whiteman, (703) 872-9306 on October 28, 2004.

Dated: October 28, 2004

Shelley Butz